

REMARKS

Claims 16-31 and 47-88 have been cancelled. Claims 32-46 are pending. The title has been amended. No new matter has been added by virtue of the amendment.

The title was objected to as not descriptive.

Applicants have amended the title to reflect the presently claimed subject matter.

Reconsideration and withdrawal of the objection is requested.

Claims 32-46 were rejected under 35 USC §101 and 35 USC §112 as drawn to an invention with no apparent or disclosed patentable utility. The rejection is traversed.

Applicants respectfully submit the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701. As acknowledged by the Examiner, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. In addition, the specification sets forth use of the described compositions in methods for diagnostics and identification of therapeutics for disorders, including, for example, metabolic disorders. Applicants submit the utility of diagnostics and screening methods for identification of therapeutics is a well established and accepted substantial and real world utility in the pharmaceutical industry. Applicants' assertion of utility is based, not only on the homology of the identified compositions, but in conjunction with scientific exemplification set forth in Example 9 demonstrating specific expression patterns.

Applicants submit the Examiner has not met the requisite standard of the Utility Guideline requirements to establish a *prima facie* showing of no specific and substantial credible utility to rebut Applicants' assertion of utility of the claimed compositions in diagnostic and/or identification of therapeutics for metabolic disease. Such a showing requires the Examiner **must**:

*...establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:*

- (A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;*
- (B) Support for factual findings relied upon in reaching this conclusion; and*
- (C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art. See MPEP 2107.02*

• **Practitioner's Docket No. MPI1997-018CP1DV1**

Applicants submit the Examiner has not made a sufficient showing to establish more likely than not the utility set forth in the present specification would not be specific or substantial, as sufficient support or factual findings have not been relied upon to make such a showing to rebut Applicant's assertion that the use in diagnostics and/or identification of therapeutics would more likely than not be useful. Rather, the Examiner relies on general arguments to back up his claim that Applicant's original assertion is incorrect. Still further, Applicants submit concurrently herewith an independent publication and the corresponding PCT publication (English abstract submitted) of a separate group identifying I5E as a G protein coupled receptor and cognate ligands. This publication supports Applicants' original assertion of I5E being a G-protein coupled receptor useful in identification of compounds capable of modulating I5E which can be useful for treating, for example digestive disorders. See, e.g., International publication no: WO02/062996 abstract.

Thus, Applicants submit the utility asserted in the specification as filed is sufficient to support a credible, substantial, and specific utility to meet the requisite standard for utility under the present guidelines of the USPTO that the presently claimed compositions are useful in the identification of diagnostics and methods for identification of therapeutics for metabolic diseases. Even assuming, however, the Examiner has made a sufficient argument for a *prima facie* showing to question the specific and substantial utility which Applicants have set forth, Applicants' submissions and arguments have met the requisite standard to sufficiently rebut such a showing. Applicants thus respectfully submit the Examiner's maintenance of the rejection under 35 USC §101 and §112 are improper and should be withdrawn. Such action is respectfully requested.

Claims 32-46 were rejected under 35 USC 112, first paragraph, as not enabling one of skill in the art to use the invention commensurate in scope with the claims because "the specification does not disclose the nexus between the I5E polypeptide and an immune, central nervous system or metabolic disorder, cognitive disorder, multiple sclerosis or depression..." See Official Action page 6, last paragraph.

Applicants respectfully traverse the rejection, and submit the breadth of the claims is not undue in view of Applicant's specification as filed and the skill of one in the art. The examiner has acknowledged Applicant's description of the compositions of an isolated DNA encoding a protein and the protein encoded thereby at page 3 of the Office Action. Rather the Examiner is held to the idea that the claims are not enabled because a definitive *in vivo* clinical proof of a nexus between I5E activity and/or expression and disease state has not been shown. Applicants respectfully point out to the examiner that the present claims are not limited to methods of treatment of particular indications, but rather are directed to methods for identification of compounds which modulate I5E. Applicants have in fact provided

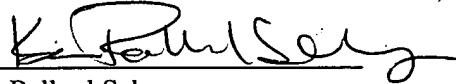
Practitioner's Docket No. MPI1997-018CP1DV1

sufficient disclosure of the sequences and methods in order to carry out the present claims. The Examiner's attention is directed, for example to section 5.4 of the application at pages 28-52, containing full description of the compositions and methods for use in practicing the present claims. Reconsideration and withdrawal of the rejection is thus respectfully requested.

This paper is being filed timely, as a request for a one month extension of time is filed herewith, and it is believed no additional fees or extensions of time are required in connection with the present submission. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested. It is believed the application is presently in a state for immediate allowance, which action is earnestly solicited.

Respectfully submitted,

<u>03 March 2003</u>	<p>MILLENNIUM PHARMACEUTICALS, INC. By  Kerri Pollard Schray Registration No. 47,066 75 Sidney Street Cambridge, MA 02139 Telephone - 617-551-3676 Facsimile - 617-551-8820</p>
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